IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC. 150 Signet Drive Weston, Ontario M9L 1T9 Plaintiff, v. CEPHALON, INC. 41 Moores Road Frazer, PA 19355 Defendant.	:	CIVIL ACTION No.: JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Apotex, Inc. ("Plaintiff" or "Apotex"), by and through its attorneys, for its Complaint against defendant Cephalon, Inc., ("Defendant" or "Cephalon") complains as follows:

NATURE OF THE ACTION

1. Apotex brings claims for declaratory relief that Cephalon's United States Patent No. 7,297,346 ("the '346 patent") is invalid or not infringed so the Federal Food and Drug Administration ("FDA") can provide Apotex final approval to market its generic version of the drug Provigil®.

PARTIES

2. Apotex is a corporation organized and existing under the laws of Canada, whose principal place of business is located in Ontario, Canada.

3. Cephalon is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

JURISDICTION AND VENUE

4. This Complaint arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over this Complaint pursuant to 28 U.S.C. §§ 1331, and 1338(a).

6. This Court has personal subject matter jurisdiction over Cephalon because it transacts business in this district, at least by selling and/or distributing pharmaceuticals in this district including Provigil®.

7. Venue is proper in this District under 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

A. THE REGULATORY BACKGROUND PURSUANT TO WHICH GENERIC SUBSTITUTES FOR BRAND NAME DRUGS ARE APPROVED

8. In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly

referred to as the Hatch-Waxman Amendments. *See* Pub.L.No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S. §355 and 35 U.S.C. §271(e)). The Hatch-Waxman Amendments were designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

9. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers wanting to sell a new drug compound must obtain approval to sell from the FDA by filing a New Drug Application ("NDA"). An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

10. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA in order to obtain FDA approval to sell a generic equivalent of a marketed drug. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

11. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the proposed generic product is bioequivalent to the branded drug.

12. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman provided brand drug manufacturers certain non-patent exclusivities, such as Orphan Drug and New Chemical Entitiy ("NCE") exclusivities.

13. When the FDA approves a brand name manufacturer's NDA, the FDA publishes in the "Approved Drug Products with Therapeutic Equivalence Evaluations",

or the "Orange Book", any patents the brand manufacturer alleges can be reasonably asserted against a generic equivalent. 21 U.S.C. §355(j)(7)(A)(iii). The listing of patents in the Orange Book by the FDA is a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer. After the NDA is approved, the brand manufacturer may list additional new patents in the Orange Book as being related to the drug the subject of its NDA. The brand manufacturer must certify, *inter alia,* that the new patents claim either the approved drug (for compound patents) or that the patents claim approved methods of using the drug (for method-of-use patents).

14. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a branded drug without receiving a license by the branded drug manufacturer), a generic manufacturer must certify the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book or the listed patents are invalid. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturers proposed product (a "Paragraph IV certification").

21 U.S.C. §355(j)(2)(A)(vii).

15. If a generic manufacturer files a Paragraph IV certification claiming a patent listed in the Orange Book is invalid or will not be infringed, a brand manufacturer

has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market.

16. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. Under the statute, submitting a Paragraph IV certification is an act of infringement. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii).

17. The first ANDA holder (first generic filer) to file a Paragraph IV certification can obtain a 180-day period of exclusivity, during which time the FDA will not approve any other ANDAs containing Paragraph IV certifications that list the same pioneer drug.

18. The FDA has interpreted Hatch-Waxman to provide first-filing generics with a 180-day exclusivity period that can be triggered by a court decision of invalidity or non-infringement or by one of the first-filing generics entering the market. 21 U.S.C. § 355(j)(5)(B)(iv). Until one of these triggers occurs, the FDA will not grant a generic that files its Paragraph IV Certification after the first filer final approval to enter the market with a generic drug. The court decision of invalidity or non-infringement can be from any case; it need not arise from a litigation against one of the first-filing generics.

B. THE SPECIFIC DRUG AT ISSUE HERE.

19. Upon information and belief formed after an inquiry reasonable under the circumstances, Provigil® is a branded drug manufactured by Cephalon. Provigil® is marketed as a "wakefulness promoting agent" used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active pharmaceutical ingredient in Provigil® is modafinil.

20. Upon information and belief formed after an inquiry reasonable under the circumstances, the FDA approved Cephalon's NDA for Provigil® on December 24, 1998, and Cephalon began selling Provigil® shortly thereafter. Because modafinil constituted an NCE, Cephalon received five years of NCE exclusivity. Provigil®'s NCE exclusivity expired on December 24, 2003.

21. Upon information and belief formed after an inquiry reasonable under the circumstances, likewise because Cephalon represented to the FDA that modafinil was a drug to treat a rare disorder (narcolepsy), Cephalon received Orphan Drug exclusivity, which expired on December 24, 2005.

22. Cephalon is the assignee of the '346 patent. Cephalon listed the '346 patent in the FDA's Orange Book as a patent that could reasonably be asserted against a generic manufacturer of Provigil®.

23. Cephalon previously listed United States Patent Number RE 37,516 ("RE '516") in the FDA's Orange Book. On December 24, 2002, four other generic manufacturers, Barr (Barr Laboratories, Inc), Mylan (Mylan Laboratories, Inc.), Teva (Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.), and Ranbaxy (Ranbaxy Laboratories, Ltd., and Ranbaxy Pharmaceuticals, Inc.) (all four

generics together are referred to herein as "the First-Filing Generics") each filed an ANDA with a Paragraph IV certification with the FDA asserting the RE '516 Patent was invalid or not infringed.

24. Cephalon initiated lawsuits against each of the First-Filing Generics. Cephalon and each of the First-Filing Generics settled their respective lawsuits. Not one of the First-Filing Generics has entered the market with a generic version of Provigil®. As a result, the 180-day exclusivity period has not been triggered.

C. APOTEX'S ANDA AND INJURY RESULTING FROM BEING HELD OUT OF THE MARKET BY CEPHALON'S LISTING OF THE RE '516 PATENT.

25. Apotex manufactures for sale both in Canada and the United States a number of generic drugs. Apotex produces more than 260 generic pharmaceuticals in over 4000 dosages and formats to over 115 countries around the world. Apotex has become familiar with the regulatory requirements for filing an ANDA and the benefits that the first to file generic manufacturer receives.

26. Apotex expended considerable effort and resources to develop a generic version of modafinil therapeutically bio-equivalent to Cephalon's Provigil®.

27. On March 30, 2005, Apotex filed ANDA number 77-667 for a generic version of Provigil®. Apotex originally included a Paragraph III certification stating it would not sell its generic product until the listed patents expired. Apotex thereafter amended its ANDA to include a paragraph IV certification as to the RE '516 patent.

28. Apotex's provided Cephalon notice it had amended its ANDA to include a Paragraph IV certification. Cephalon did not file a lawsuit in response to that certification, so Apotex filed, *inter alia*, a declaratory judgment action asserting the RE

'516 patent is invalid, not infringed, and unenforceable. That suit is currently pending in this jurisdiction, Apotex, Inc. v. Cephalon, Inc. et al., 2:06-cv-2768.

29. More recently, Cephalon listed the '346 patent in the FDA's Orange Book. Apotex amended its ANDA No. 77-667 to include a paragraph IV certification as to the '346 patent and served notice of the same to Cephalon via Registered Mail received by Cephalon on or about February 17, 2009. At least 45 days have passed since Cephalon received this notice, and Cephalon has not filed a patent infringement action.

30. By filing a substantially complete ANDA for modafinil with the FDA, Apotex has taken all regulatory actions necessary to obtain FDA approval of its ANDA thereby allowing it to sell generic Provigil® in the United States.

31. Apotex has obtained tentative approval from the FDA to sell modafinil tablets, 100 mg and 200 mg. "Tentative approval" means the generic product the subject of the ANDA is deemed by FDA to be safe, effective and bioequivalent to its brand name counterpart, but the existence of some legal or regulatory barrier precludes the FDA from granting final approval to sell. The FDA granted tentative approval based on Apotex's submissions to the FDA. The FDA determination was based on the status of current good manufacturing practices of the facilities used in the manufacture and testing of modafinil.

32. Even though Apotex has tentative approval, Apotex does not have final approval for its ANDA and cannot sell a generic version of Provigil®.

33. Upon information and belief formed after an inquiry reasonable under the circumstances, the FDA will not give final approval to Apotex's ANDA unless (1) one or more of the Generic Defendants begin to market their generic version of Provigil® or (2) there is a court decision finding, *inter alia*, the '346 patent invalid or not infringed.

34. Cephalon's settlement agreements with the First-Filing Generics provide those companies will not market a generic version of Provigil® and trigger the 180-day exclusivity until at least 2012.

35. Apotex is injured because Cephalon's '346 patent is preventing the FDA from giving Apotex final approval to market its modafinil drug product as a therapeutic equivalent to Cephalon's Provigil® because the 180 day period of marketing exclusivity given to the Generic Defendants will not begin until the Generic Defendants enter the market in 2012. Even after that period, Apotex needs a finding of invalidity or non-infringement of the '346 patent to have certainty that it does not infringe the '346 patent.

36. Apotex, in being prevented and delayed from entering the market for modafinil as a consequence of Cephalon's actions including listing the '346 patent in the FDA's Orange Book, has suffered, and will continue to suffer actual damages.

37. Delay in the approval of Apotex's ANDA application has caused, and is causing, substantial damage to Apotex .

D. FACTS DEMONSTRATING APOTEX STATES A JUSTICIABLE CLAIM OR CONTROVERSY.

38. Upon receiving final approval of its ANDA for modafinil from the FDA, Apotex is prepared and fully intends to enter the U.S. market with a generic version of Provigil®.

39. Apotex's generic Provigil® drug would not infringe a valid and enforceable claim of the '346 patent. Apotex suffers the injury of the restraint on the free exploitation of its non-infringing generic version of Provigil®.

40. Apotex is being excluded from selling its non-infringing modafinil tablets because Cephalon has taken actions that delay the FDA from approving Apotex's ANDA. Apotex cannot enter the market without FDA approval.

41. Apotex has the right to enter the generic modafinil market, but cannot enter the market because of Cephalon's actions, including but not limited to Cephalon's decision to list the '346 patent in the FDA's Orange Book.

42. Cephalon is using its Orange Book listed '346 patent to exclude Apotex from the modafinil market. If Cephalon had not listed any patents in the FDA's Orange Book, Apotex would be able to enter the market.

43. Cephalon's listing of its '346 patents in the FDA's Orange Book effectively denies Apotex an economic opportunity to enter the marketplace unless Apotex can obtain a judgment that the patent is invalid or not infringed.

44. Cephalon's listing of its '346 patent in the FDA's Orange Book creates a barrier to competition against Apotex.

45. Apotex has a complete generic drug product application and there are no additional facts required to determine whether Apotex's ANDA infringes a valid and enforceable claim of Cephalon's '346 patent.

46. If the Court withheld consideration of Apotex's declaratory judgment claims, it would have the immediate and substantial impact of forestalling Apotex's ability to trigger the 180-day exclusivity period and enter the market, especially in conjunction with the declaratory judgment suit challenging the RE '516 patent, or immediately upon the expiration of any exclusivities relating to the RE '516 patent, or immediately upon the expiration of any exclusivities after the First-Filing Generics enter

the market. In sum, delaying consideration of the invalidity and infringement of the '346 patent delays the date on which the FDA would grant Apotex final approval, injuring Apotex.

47. Cephalon has not offered a covenant not to sue. However, even if Cephalon were to make such an offer, it would not moot this action because Apotex's injury of being unable to sell a non-infringing generic version of modafinil would not be alleviated.

COUNT I

DECLARATORY JUDGMENT CLAIM OF PATENT INVALIDITY AGAINST CEPHALON

48. Paragraphs 1-47 above are hereby adopted by reference as though they were fully set forth herein.

49. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

50. Apotex has filed an ANDA with a Paragraph IV certification that the '346 patent is invalid and/or not infringed by Apotex. Apotex intends to sell modafinil once it obtains FDA approval. There is a real, actual, and continuing justiciable case and controversy between Apotex on the one hand and Cephalon on the other hand regarding the invalidity of the '346 patent.

51. The '346 patent is invalid on the grounds specified in United States Code, Title 35, including, but not limited to, failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

52. Apotex is entitled to a judicial declaration that the claims of the '346 patents are invalid.

COUNT II

DECLARATORY JUDGMENT OF NON-INFRINGEMENT AGAINST CEPHALON

53. Paragraphs 1-50 above are hereby adopted by reference as though they were fully set forth herein.

54. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. Apotex has filed an ANDA with a Paragraph IV certification that the '346 patent is not infringed by Apotex. Apotex intends to sell modafinil once it obtains FDA approval. There is a real, actual, and continuing justiciable case and controversy between Apotex on the one hand and Cephalon on the other hand regarding the infringement of the '346 patent.

56. The '346 patent will not be infringed by the manufacture, use, or sale of the generic modafinil for which Apotex has submitted an ANDA.

57. Apotex is entitled to a judicial declaration that the manufacture, sale or use of Apotex's modafinil product, that is the subject of ANDA No. 77-667, will not infringe, directly or indirectly, any valid claim of the '346 patent.

DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex prays for judgment:

a. Finding Apotex has not infringed the '346 patent;

b. Finding the '346 patent invalid;

c. Finding this to be an exceptional case under 35 U.S.C. § 285;

d. Awarding Apotex its costs, expenses, and reasonable attorneys' fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex demands trial by jury for all issues triable by jury as a matter of right.

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